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Draft Meeting Minutes – December 20, 2012 P&T Committee

Nevada State Health Division
3811 W. Charleston Blvd, Suite 112
Las Vegas, NV 89102

Committee Members Present:

Las Vegas: Adam Zold, Pharm.D.' Evelyn Chu, Pharm.D.; Shamim Nagy, MD; Weldon Havins, MD; Joseph Adashek, MD; Constance Kalinowski, MD; Ronald Shockley, MD
Carson City: Kevin Desmond, RPh; Michael Hautekeet, RPh; David Fluitt, Pharm.D.

Others Present:
DHCFP:
Las Vegas: Gariel Lither, Deputy Attorney General
Carson City: Coleen Lawrence, Chief Program Services; Mary Griffith, RN, Social Services Program Specialist

Catamaran:
Las Vegas: Carl Jeffery, Pharm.D.; Kevin Whittington, RPh
Carson City: Mariellen Rich, RPh; Irene Tobarak

HPES:
Carson City: Ed Arnold, PBM Liaison

Others:
Las Vegas: Steve Farmer, Amgen; Vinson Lee, Amgen; Brad Budits, Elan; Dave Chapman, UCB; Lovell Robinson, Abbott; Doug Powell, Forrest; Troy Sheldon, Forrest; Kara Sperandeo, Forrest; Marc Shaw, Forrest; Jennifer Dondson, Aplolis; Lori Hawarth, Bayer; Krystal Joy, Otsuka; Phil Walsh, Sunovion; Scott Larson, BMS; Ben Skoog,Abbott; Aimee Heill; Melissa Walsh, Novartis; Helen Liao, Lilly; Joe Busby, Lilly; Camille Kerr, Allergan; Michael Foster, Celgene; Robert Green, Celgene
Carson City: None

AGENDA

I. Call to Order and Roll Call

Meeting called to order at 1:03 PM

Roll Call Taken

Joseph Adashek, MD: Joseph Adashek, here

Weldon Havins, MD: Weldon Havins, here

Ronald Shockly, MD: Ronald Shockly, here

Evelyn Chu, Pharm.D.: Evelyn Chu, here

Adam Zold, Pharm.D.: Adam Zold, here

Kevin Whittington: Kevin Whittington, Catamaran, here

Carl Jeffery: Carl Jeffery, with Catamaran, here

Gabriel Lither: Gabriel Lither, Deputy Attorney General's office, here

Chairwoman Shamim Nagy, MD: Shamim Nagy, here

Constance Kalinowski, MD: Constance Kalinowski, here

Michael Hautekeet, RPh: Mike Hautekeet, here

Kevin Desmond, RPh: Kevin Desmond, here

David Fluitt, Pharm.D.: David Fluitt, here

II. Public Comment

Chairwoman Shamim Nagy, MD: Public comment from Reno?

Coleen Lawrence: There is no public comment from the North

Gabriel Lither: Any public comment from the South on any matter? You will get another chance to comment as we call each class.

III. Review and Approval of the November 8, 2012 Meeting Minutes

Chairwoman Shamim Nagy, MD: Motion to approve minutes?

Joseph Adashek, MD: I move that we approve the minutes from the last meeting.

Constance Kalinowski, MD: Second

Chairwoman Shamim Nagy, MD: All in favor?

Board Members: Unanimous, "Aye"

Chairwoman Shamim Nagy, MD: Motion carries

IV. Status Update by DHCFP

A. Public Comment

None

B. Program Updates

Chairwoman Shamim Nagy, MD: Status update from the State?

Coleen Lawrence: Good afternoon Madam Chairman and members. For clarification, Gabe, can you let me know who the last member in the South that will be voting so we know when to continue voting in the North?

Gabriel Lither: Ok, we will have Dr. Nagy as the last person to vote from the South. So when you hear her vote, that will be the last vote down here.

Coleen Lawrence: Ok, thank you. Status updates. First of all, I need to do a friendly reminder for the members, because I have had some information come into the division. I just want to remind the members that you are not obligated by any means to receive any contact or information by pharmaceutical manufactures on behalf of the pharmaceutical and therapeutics committee outside of this meeting. So please do not feel you have to take on any information outside of this committee meeting that is scheduled. That is why we have plenty of public comment scheduled through the agenda. I want to make sure that is very clear. As far as other updates, we are in the middle of getting ready for the legislative session. It will be a very busy time for us. We are also trying to schedule meeting for the upcoming year. Please watch for the scheduling of when the meetings are and where they will be held. Because of the legislature, those meeting may have to change. I caution everyone who watches the agenda to be careful of where we are going to be at and watch the agendas. Other than that, I don't have any other new information.

Carl Jeffery: Coleen, do you want to introduce the new member that is up there with you?

Coleen Lawrence: I will, yes, I will have David introduce himself and give some background.

David Fluitt, Pharm.D.: Yes, sorry I wasn't able to make it to the last meeting, I wasn't able to coordinate everything at the last minute. My name is David Fluitt. I am a pharmacist who currently has a shared position as the pharmacy manager at the Carson City store and I manage the district in Nevada. I also work at Sierra Surgery Center to keep my hands in the hospital sector. I have also done some long term care consulting and I have also been doing some medical mission work since 2006 in Guatemala and Haiti. I am grateful to be here and hopefully I can make a positive impact on the committee.

Coleen Lawrence: And that means nobody scare him away at his first meeting.

V. Established Drug Classes

A. AntiParkinson's Agents: Non-Ergot Dopamine Agonists

Chairwoman Shamim Nagy, MD: We will open up with established drug classes, antiparkinson agents. Any public comment?

David Chapman: Good afternoon, my name is Dr. David Chapman, I am the medical science liaison with UBS. I am here speaking to you on behalf of Neupro or rotigotine transdermal system. Neupro is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease as well as for the treatment of moderate-to-severe primary restless leg syndrome. Neupro is the first and only dopamine agonist transdermal patch which provides continuous stable 24 hour drug delivery. Therefore we ask that you provide unrestricted formulary access to this therapy. The effectiveness for Parkinson's disease was demonstrated in randomized clinical trials in early stage patients, so those who were not receiving concomitant levodopa therapy as well as advanced stage Parkinson's disease patients, those who were receiving concomitant levodopa. Neupro is also indicated for the treatment of moderate to severe primary restless leg syndrome, or RLS. The severity of RLS can range from mild and infrequent symptoms to very severe debilitating symptoms that can crop up on a daily basis. The effectiveness for restless leg syndrome was demonstrated in randomized clinical trials that lasted 6 months in duration in patients with moderate to severe RLS. Because Neupro is a transdermal system, the pharmacokinetics of the active ingredient, rotigotine, should not be affected by food intake. Furthermore, there are no dosage adjustments needed for patients who are renally impaired or patients who have mild to moderate hepatic impairment and there are no dosage adjustments needed based on gender or age. Neupro is contraindicated in individuals who have a history of hypersensitivity of either rotigotine or ingredients in the transdermal system. Neupro is associated with important warnings and precautions including allergic type hypersensitivity to the ingredient sodium metabisulfite, falling asleep while engaged in activities of daily living, somnolence, hallucination, and psychotic like behaviors, symptomatic hypotension, syncope, impulse control disorders or compulsive behaviors, elevation of blood pressure and heart rate, fluid retention, and weight gain, dyskinesia, application site reactions, melanoma and augmentation and rebound. I would like you to refer to the full prescribing information found in the PI. In terms of the most common adverse events, this was defined as occurring in greater than 5% greater than placebo for the highest doses of rotigatine, for the treatment of Parkinson's disease, those adverse events are nausea, vomiting, somnolence, application site reactions, dizziness, anorexia, hyperhidrosis, insomnia, peripheral edema and dyskinesias. The most common adverse reactions for the treatment of restless leg syndrome, with Neupro, include application site reaction, somnolence, headache and nausea. Due to extensive first pass metabolism, rotigotine cannot be administered orally. Neupro is a transdermal delivery system, designed to bypass the gastrointestinal tract. Therefore Neupro is an option for patients experiencing swallowing and or gastric emptying difficulties. In disease state studies, looking at Parkinson's disease patients, at some point during disease progression up to 100% of patients have gastroparesis or delayed gastric emptying of solids and up to 97% of Parkinson's disease patients have dysphagia or difficulty swallowing. Note that Neupro can cause nausea, vomiting and gastrointestinal distress, which might occur more frequently during initial therapy. In conclusion, Neupro has demonstrated efficacy both in early and advanced stage Parkinson's disease patients, as well as patient that suffer restless leg syndrome. Its innovative transdermal delivery provides continuous stable drug delivery. I hope I was able to demonstrate the

value to you of Neupro for appropriate Medicaid patients with Parkinson's disease and restless leg syndrome. And would like to ask you provide unrestricted access to this therapy. Lastly for a copy of the Neupro prescribing information for your review, please visit Neupro.com. Additionally, your PBM has been supplied with copies. Please refer to this prescribing information for detailed information regarding the safety and efficacy of Neupro. With that I think you for your time, and I would like to address any questions you may have.

Weldon Havins, MD: You identified yourself as "Doctor", are you a physician or are you a Pharm.D.?

David Chapman: I am a Ph.D. in pharmacology.

Chairwoman Shamim Nagy, MD: Any questions?

Gabriel Lither: Any questions up North? No? Any additional public comment? No? Thank you.

Chairwoman Shamim Nagy, MD: No other comment in Reno?

Coleen Lawrence: No comment here in the North.

Carl Jeffery: Currently, you can see on the screen, we have pramipexole, ropinirole, and ropinirole ER as current PDL, and the only non-preferred drug is the Mirapex ER. With the addition of Neupro, this is what prompted us to review this class. As you may remember, this product was introduced back in 2008, it was short lived due to manufacturing problems where the gel was crystalizing. I assume they have solved the problem with the crystalizing patches. There are three agents we are looking at, Mirapex, Requip and Neupro. All of them work the same way, they are non-ergot dopamine agonists. They have similar adverse effect profiles. The pramipexole has a little more incidence of hallucinations compared to some of the others. The ropineral with somnolence and hypertension. All three have warnings regarding falling asleep during activities of daily living. You're not supposed to use it while driving or performing other dangerous activites. Renal impairment isn't a big deal, but does need to be considered with pramipexole. Ropinirole on the other hand goes through the liver, the 1A2 enzyme, so there are some potential drug interactions. And all are indicated for the same thing, the signs and symptoms of Parkinson's disease. It is our recommendation that these agents be consider therapeutically equivalent.

Joseph Adashek, MD: I move that we accept the recommendation that they are therapeutic alternatives.

Adam Zold, Pharm.D.: I second.

Chairwoman Shamim Nagy, MD: Any discussion? Up in Reno, any comment? Voting.

Board members: Unanimous, "Aye"

Chairwoman Shamim Nagy, MD: Motion approved. Now for inclusion of the medications.

Carl Jeffery: When you look at the differentiation between the products, there really are not any head-to-head studies among the different products. There is one study that was done with the Neupro patches with the pramipexole immediate release. It was shown the median off-time was reduced. Other than that, there are not any head-to-head studies showing one is better than the others. Patients

treated with Neupro transdermal patches or the oral agents receive the same benefit. Our recommendation to make preferred the generic pramipexole, generic ropinirole, ropineral ER and Neupro. That would leave just the brand Mirapex as non-preferred.

Chairwoman Shamim Nagy, MD: Need a motion?

Joseph Adashek, MD: I move we accept the recommendations, this is Adashek.

Adam Zold, Pharm.D.: I second.

Chairwoman Shamim Nagy, MD: Any discussion? Any comments up in Reno? Move to voting.

Board members: Unanimous, "Aye"

Chairwoman Shamim Nagy, MD: Motion approved.

B. Acne Agents: Topical, Retinoid Agents and Combinations

Chairwoman Shamim Nagy, MD: The next class is acne agents. Any public comment in Las Vegas? None here, up in Reno?

Coleen Lawrence: No comment from the North.

Chairwoman Shamim Nagy, MD: So clinical presentation.

Carl Jeffery: Currently we have on the list, it is the same that is in your binder, there is a copy of the PDL. On the PDL we have adapelene, Retin-A Micro and the Epiduo, and all the others are considered non-preferred. The topical retinoids have become the first line mainstay of acne treatment. Because they result in the reduction in the formation of the papules and comedomes and the microcomidones, and they change the features of the skin to facility the benefit of the topical antibiotics, to make them a little more effective. There are three products that have only the retinoid products in them, Differin or generic adapalene, Tazorac or tazarotene and the tretinoin which has multiple products. The difference with the Retina-A Micro is that it has a micro-capsule to help decrease the amount irritation associated with some of the other products. All are approved for the indication for the topical treatment of acne vulgaris. There are two combination products that are combined with a topical antibiotic, Epiduo which is currently preferred has a mixture of adapalene with benzoyl peroxide and the newer product Ziana that is a mixture of tretinoin and clindamycin. Both are FDA approved for the treatment of acne vlulgaris in patients 12 years and older. Our recommendation is that all these products be consider therapeutic alternatives.

Chairwoman Shamim Nagy, MD: Do we have a motion to approve?

Joseph Adashek, MD: I move that we accept the recommendation.

Evelyn Chu, Pharm.D.: I second it, Chu.

Chairwoman Shamim Nagy, MD: Any discussion? No comments in Las Vegas, any in Reno? No? Move into voting.

Board members: Unanimous, "Aye"

Chairwoman Shamim Nagy, MD: Motion approved, move into drugs for inclusion.

Carl Jeffery: The retinoids have been a mainstay of treatment and been show to provide significant improvement with the addition of these agents. The Retin-A Mirco is a microsphere gel, it is the only one like this, and it is designed to decrease the irritation that some of the others can cause. And the topical combination products have been shown to have some significant effectiveness over some of the other single agent products. Our recommendation is to keep the Retin-A micro, but to add the Tazorac and also to change out to the Ziana for the one combination product. We wanted at least one combination product as a preferred, and the Ziana shows it has some benefits.

Joseph Adashek, MD: I move that we accept the recommendations.

Constance Kalinowski, MD: Second

Chairwoman Shamim Nagy, MD: Any discussion? Move to voting.

Board members: Nine members vote, "Aye", one "Nay".
Chairwoman Shamim Nagy, MD: Motion approved.

C. Gastrointestinal Agents: Pancreatic Enzymes

Chairwoman Shamim Nagy, MD: We move to gastrointestinal agents, pancreatic enzymes. Public comment?

Coleen Lawrence: No comment up here in the North.

Chairwoman Shamim Nagy, MD: We have one here in Las Vegas.

Ben Skoog: Hi I'm Dr. Ben Skoog, I'm a pharmacist for Abbott Laboratories, I'm on the clinical evidence and outcomes team. I'm here today to talk about Creon. The committee is encouraged to review the full PI for comprehensive safety and efficacy information. Today I would like to share with you three key points about Creon, or this class of drugs. Number 1, nutritional status is vital to the long-term survival of CF patients. Number 2, Creon is the first FDA approved delayed release pancreatic enzyme to be marketed in the U.S. and it is the only one with the indication for the treatment of exocrine pancreatic insufficiency due to CF, chronic pancreatitis and pancreatectomy. Number 3, Creon is not interchangeable with any other pancrealipase product and product substitution is not recommended in this class. So number 1, with the nutritional status is vital to the long-term survival of patients with CF, the CF foundation recommends that the prevention of malnutrition be the primary nutritional goal in management of these patients. Number 2, Creon is the first FDA approved enzyme, as I mention before, and it is the only one indicated for EPI due to CF, pancreatectomy and other conditions. So two pivotal studies and one chronic pancreatitis/pancreatectomy trial evaluated the safety and efficacy of Creon in adults and children with EPI due to CF, and adults with EPI due to chronic pancreatitis. So the main efficacy endpoints in these trials is the mean difference in the coefficient of fat absorption between Creon and placebo. A statistically higher CFA was seen with Creon compared to placebo in all the trials. From a safety standpoint, Creon was also evaluated in these pivotal trials as well. GI complaints, cough, dizziness and headache are the most commonly reported adverse events. Fibrosing colonopathy has been reported following treatment with different pancreatic enzyme products, so patients with fibrosing colonopathy should be monitored closely because some of these patients may be at risk for progressing to stricture. Care should be taken to assure that no drug is

retained in the mouth of these patients. Creon should not be crushed, chewed or mixed in foods having a pH greater than 4.5, so it should be put in acidic foods if the patient cannot take the capsules whole. These actions can disrupt the protective enteric coating resulting in an early release of the enzyme causing irritation of the mouth and loss of enzyme activity. Creon is available in 3,000 lipase unit strengths recently approved, and also 6,000, 12,000 and 24,000. It should be initiated in patients at the lowest recommended dose and the dose gradually increased as consistent with the CF Foundation Consensus Conferences. Creon dosing similar to other therapies is highly individualized in these patients and is based on the fat ingestion or the actual body weight. And then based on clinical symptoms and the steatorrhea and dietary fat content in these patients. Lastly, product substitution is not recommended. Creon is not interchangeable with any other pancrealipase products. Pancreatic enzyme products are not absorbed in the GI tract as you might know in any appreciable amount. There are no pancreatic enzyme bioequivalent ratings, for example in the Orange Book, so no AB ratings. Lastly, Creon is the number 1 prescribed pancreatic enzyme in the US. So in summary I talked about three key points and nutritional status is vital to survival in these patients. Number 2, Creon was the first FDA approved enzyme in the US and it has the indication for CF, chronic pancreatitis and pancreatectomy. And number 3, Creon is not interchangeable with any other product. I ask that the committee maintain preferred status for Creon. Thank you for your time today.

Chairwoman Shamim Nagy, MD: Any questions? In Reno? None, thank you.

Gabriel Lither: Any other public comment? Not in the South, any in the North?

Coleen Lawrence: None up here in the North.

Chairwoman Shamim Nagy, MD: Ok, Catamaran for drug inclusion.

Carl Jeffery: This is our third consecutive meeting with the pancreatic enzymes, I think we may be done for a while. There are two new products on the market, we just talked about this a little over a month ago, the Pertyze and the Ultresa are the two new products. As with the others, similar information. The reason they need these as explained to is something kind of insufficiency to the enzyme is being produced. So either the pancreas has been removed or there is some other disease that is causing it such as cystic fibrosis. There is a letter from the Cystic Fibrosis Foundation included in the information handed out today. The six products that are currently available, they are all approved for the pancreatic insufficiency. They are only different in the concentrations of the enzymes they each have with the lipase, amylase and protease amounts in each one. All the products are from porcine origin and contain the same mixture of digestive enzymes lipase, protease and amylase. The only difference is the concentrations, but the manufacture recommend starting with the same levels across the board. Our recommendation is that they all be considered therapeutically equivalent.

Ronald Shockly, MD: I make the motion to consider these therapeutically equivalent.

Weldon Havins, MD: I second

Chairwoman Shamim Nagy, MD: Any discussion?

Board Members: unanimous, “Aye”

Chairwoman Shamim Nagy, MD: Motion approved, move to the drug inclusion.

Carl Jeffery: Despite these having to go through all the FDA hoops to get approved again, there are very few clinical studies comparing the different products against each other. They are all pretty much the same product. The only one that is different is the Viokace, is not enteric coated, so it must be administered with a proton pump inhibitor in order to work. Our recommendation is to keep the Creon and then add Zenpep, all strengths. As you may remembers, we had just the generic Zenpep 5 previously, but this is all strengths of the Zenpep. And the remaining would be non-preferred.

Weldon Havins, MD: I move that we accept the proposed for Creon and Zenpep for the PDL.

Evelyn Chu, Pharm.D.: Second

Chairwoman Shamim Nagy, MD: Discussion? Any questions.

Board members: Unanimous, "Aye"

Chairwoman Shamim Nagy, MD: Motion carries.

D. Respiratory: Inhaled Anticholinergic Agents

Chairwoman Shamim Nagy, MD: Next, respiratory, inhaled anticholinergic agents. Public comments?

Coleen Lawrence: None up here in the North.

Chairwoman Shamim Nagy, MD: We have one in Vegas

Kara Sperandeo: Hello, my name is Kara Sperandeo, I'm a Pharm.D. with Forrest Research Institute. Thank you members of the Nevada State Committee for your time today in reviewing the inhaled anticholinergic class. Today I would like to introduce to you Forrest's recently approved product, Tudorza Pressair that also goes by the name of aclidinium bromide. Tudorza Pressair is a long acting antimuscarinic agent which was approved in July of 2012. It is indicated for the long-term treatment of bronchospasm associated with chronic obstructive pulmonary disease, including both chronic bronchitis and emphysema. Now a little about COPD. COPD has recently surpassed stroke to be the third leading cause of death in the United States. It is the only disease state in the top 5 whose incidence is on the rise, therefore there is a pressing need for development of additional treatment options for these patients. Now in 2011, the Global Initiative for Chronic Obstructive Lung Disease or the GOLD Guidelines, recommend long acting antimuscarinic agents as first-line treatment options for patient with moderate to very severe COPD. The efficacy and safety of Tudorza Pressair was established in three pivotal trial, 12 to 24 weeks in duration and those included adult patients with moderate to severe COPD. The primary efficacy endpoint in these trials was trough FEV^1 which is the measurement of the effectiveness of the dose at the end of the dosing interval. Tudorza resulted in an improvement from baseline trough FEV^1 of up to 124 ml at week 12. In addition serial spirometic evaluation were performed in a subset of patients in all three trials. Improvements in lung function was maintained for 12 hours and maintained consistent throughout the three or six month treatment periods. In addition patients treated with Tudorza in two of the three pivotal trial resulted in a decrease of about one puff of rescue medication per day at the end of the treatment trials. The most common adverse event occurring with Tudorza treated patients was headache, nasal pharyngitis and cough. And of note anticholinergic adverse events such as dry mouth and constipation were reported at less than 1% in aclidinium treated patients. This has a lot to do with the drug's pharmacokinetics. Tudorza is rapidly and extensively

hydrolyzed in the plasma to two metabolites which are devoid of pharmacological activity. This mean low systemic exposure. In addition, aclidinium is also rapidly eliminated by hydrolysis as well, with urinary excretion accounting for only 0.9% of the dose. Because of this, there are no warnings or precautions associated with Tudorza being used in patients with renal impairment. Now there were no formal drug-drug interactions completed because of those pharmacokinetics and because in vitro studies show no inhibition of CYP450 enzyme system. Tudorza has no contraindications associated with it, but five warnings and precautions. It is not to be used for acute use. Paradoxical bronchospasm may occur as with worsening of narrow angle glaucoma or urinary retention. Finally, if individuals have hypersensitivity reactions to atropine, it should be used with caution and if they have hypersensitivity to milk proteins as lactose is a carrier in the device. Now the recommended dose of Tudorza Pressair is 400mcg provided as one oral inhalation given twice a day. And we know successful oral inhalation therapy depends not only on effective drug but on reliable inhalers. What you see here is the Pressair inhaler device. It is breath-actuated, dry powder, multi-dose inhaler. It provides multiple auditory and visual feedback mechanisms for the patient. To administer the dose, the patient will press and release the button. At that time, this color controlled window changes from red to green, letting the patient know the dose is ready. As the patient inhales, they hear and click and the control window will change back from green to red. Therefore the patient and the caregiver can determine that the dose was delivered. In addition, this button will lock out so the patient cannot load multiple doses in the chamber at one time. And it locks out when the inhaler is empty. Finally, there is a dose indicator letting the patient know when they need to call in for a refill. Now the Pressair device delivers target daily inspiratory flow rates as low as 35 L/min. The committee is directed to the prescribing information if they would like additional information. So in summary, COPD is the third leading cause of death in the US, and its prevalence is increasing. Therefore there is a pressing need for additional treatment options for these patients. The GOLD Guidelines recommend long-acting antimuscarinic agents as first line treatment options for patients with moderate to very severe COPD. Tudorza Pressair is a long-acting antimuscarinic agent which is FDA approved and indicated for the long-term maintenance treatment of bronchospasms associated with COPD. Its efficacy was established in three pivotal trial, 12 to 24 weeks in duration, demonstrating improvements in trough FEV^1 from baseline at up to 124 mls over placebo at week 12. In addition peak improvements were seen as early as day one, and sustained throughout the 12 to 24 week period. Finally, the most common adverse events again were headache, nasal pharyngitis and cough. So in summary, aclidinium is an alternative to other inhaled maintenance COPD therapies providing improved bronchodilation, minimal system adverse events through a user-friendly device.

Joseph Adashek, MD: Are there any prospective randomized trials comparing aclidinium to the other long acting inhalers.

Kara Sperandeo: Great question, we currently have no head-to-head data, however in the AMCP dossier, there is a study that looked at the safety and efficacy of aclidinium compared to placebo and it does have a tiotropium arm. It is a six week trial and the primary efficacy endpoint there is FEV_1 area under the curve at zero, 12 and 24 hours. So the whole area under the curve.

Chairwoman Shamim Nagy, MD: Any other question? Up in Reno? None. Thank you. Any other public comment?

Carl Jeffery: On here is the Atroven HFA inhaler, the ipratropium nebulizer, the Combivent inhaler, Spiriva and then the albuterol/impratropium nebulizer solution, the generic Duoneb. The Duoneb brand is the only non-preferred on the list. We do have the new products, the Combivent Respimat and the Tudorza, are the two new products is why we are bring this class up. The class itself is a mainstay at treating COPD, has been for several years. With the advent of the Spiriva, it really changed the treatment of COPD with the long-acting anticholinergics. They work by decreasing the parasympathetic

system to open the airways and relaxing the smooth muscle. Three single agents are currently available, the Atrovent, which the metered dose inhaler has been reformulated a few years ago to not include the CFC propellant, the new one we just heard about, Tudorza and the Spiriva that has been out for a few years. In the combination products, we have the Combivent, which is the only metered dose inhaler available at this time, the others are all nebulizer solution. The deal with the Respimat is because the current Combivent metered dose inhaler still uses the CFC's, and as a result with the Montreal Protocol, all the manufactures have to do away with the CFC propellant. They created a new deliver mechanism that is actual a spring-loaded mechanism to deliver the medication. The Tudorza is indicated for the long-term maintenance therapy of bronchospasms associated with COPD, including chronic bronchitis and emphysema. Three studies with the Tudorza as we heard about showing that it was effective. Tudorza is pregnancy category C. I think we heard a lot from the representative. Again, it is not a rescue medication. She actually gave a very nice demonstration of the new product. Our recommendation is that the products currently available in this class be considered therapeutically equivalent.

Weldon Havins, MD: I just have a question. Is there any evidence comparing Spiriva to Tudorza?

Carl Jeffery: There is nothing with Spiriva against the Tudorza, there is a Spiriva against the ipratropium, showing that is a little bit superior, but nothing with the Tudorza.

Joseph Adashek, MD: I move that we accept the recommendation that they are therapeutic alternatives.

Ronald Shockly, MD: I second.

Chairwoman Shamim Nagy, MD: Any questions?

Board Members: Unanimous, "Aye".

Chairwoman Shamim Nagy, MD: Motion carries. Presentation for preferred?

Carl Jeffery: When we look at which ones we want to make preferred, we have to evaluate the benefits with what is currently available. All have been shown to be safe and effective. Despite the limit of never had head-to-head trials, they have all been shown with slight differences. Spiriva I will point out is the only one with end-point studies with decreasing COPD exacerbations, where all the others measure FEV_1. So that is a little benefit with the studies that Spiriva has put together. The Tudorza is administered twice a day, where the Spiriva is a once a day medication, for the long-acting anticholinergic. The Respimat and the Combivent inhaler, the manufacture plans on stopping, if they haven't stopped already, producing the Combivent metered dose inhaler, they will begin creating that. It is just a matter of time before they run out of supply for the standard metered dose inhaler and is no longer available. They anticipate in January 2014 the Respimat will be the only formulation available. We are trying to be a little proactive with how we treat those. There the separate products that are available. The Combivent is a combination of albuterol which we discussed at the last meeting and the ipratropium or Atrovent. Which are available on the PDL. Our recommendation is to make Atrovent HFA, keep the Combivent until it runs out, keep the ipratropium nebs and the generic duoneb solution, the ipratropium/albuterol mixture, and the Spiriva. This is mostly because the Spiriva has known track record, the Tudorza is a relatively new product, it is given twice a day, we think the Spiriva may have some benefits.

Gabriel Lither: And just as a reminder, we did receive several pieces of correspondence from some people in the community and those will be part of the record in this case.

Weldon Havins, MD: I move we accept Catamaran's suggestions on the proposed PDL medication.

Ronald Shockly, MD: I second.

Chairwoman Shamim Nagy, MD: Any discussion? Any questions in Reno? We move to voting.

Board Members: Unanimous, "Aye".

Chairwoman Shamim Nagy, MD: Motion approved.

VI. Report by Catamaran on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Carl Jeffery: This is our RxHighlights is in the back of the binder under the named tab. I'm not going to go through a lot of this stuff, but there are a couple new products out recently, several new generic products that have become available. One of them is the Revatio, and I think we will plan on reviewing that in March. There are some other medications in that class. We currently have the Revatio on our formulary. Symbyax is another one that was a costly medication that is going generic, but that one is considered preferred or non-preferred at this time. And the other big one going generic is the Stalevo. Some other new medication, but I'm not going to read through those.

VII. Review of Next Meeting Location, Date, and Time

Chairwoman Shamim Nagy, MD: Review for the next meeting? Date, time and location?

Carl Jeffery: It is March 28th, currently we are planning on this same location unless something changes, but we will continue to do the teleconference with Carson City.

Coleen Lawrence: We are still trying to find other facilities for everybody. We have been calling around looking for other locations that can video conference.

VIII. Public Comment

Chairwoman Shamim Nagy, MD: Any public comment?

Coleen Lawrence: None in the North

Chairwoman Shamim Nagy, MD: And none in Las Vegas. Meeting adjourned.

IX. Adjournment

Meeting adjourned at 1:45 PM.